

Application Serial No. 09/720,762

Attorney Docket No. 114474.00014

Amendment and Response to Non-Final Office Action, Submitted January 8, 2007

Claim 39 (previously presented): The gasket according to claim 33, wherein the pre-filled syringe further comprises a luer lock portion formed in a nozzle of the syringe at an end of the syringe barrel opposite the gasket.

Claim 40 (previously presented): The gasket according to claim 33, wherein a second tapered slant is formed between the peripheral side surface of the gasket that contacts the inner surface of the syringe barrel and the restriction.

Claim 41 (canceled): The gasket according to claim 33, wherein only the peripheral side surface that contacts the inner surface of the syringe barrel is laminated with silicon.

#### REMARKS/ARGUMENTS

Claims 1, 3, 6-9, 11 and 13-40 are now pending, a total of 35 claims. Independent claims 1, 9, 23 and 33 are currently amended. Dependent claims 2, 4, 5, 10, 12 and 41 are canceled.

The non-final Office Action mailed July 9, 2007 withdraws the objection to the specification and rejection under 35 U.S.C. §112 that were made with respect to the limitation "only the peripheral side surface that contacts the inner surface of the syringe barrel is laminated" in claim 1, 18, 32 and 33. In addition, the July 9, 2007 Office Action withdraws the rejections under 35 U.S.C. §103(a) with respect to claims 1, 3, 6-10, 12, 16-18, 23 and 30-32, and enters new grounds of rejection under §103(a) on all pending claims.

#### I. Independent Claim 1

Claims 1, 3, 6-9, 16-18, 23 and 30-32 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Trull (U.S. 6,080,136) in view of Sudo et al. (U.S. 5,009,646).

Claim 1 is currently amended, and recites as follows:

Application Serial No. 09/720,762

Attorney Docket No. 114474.00014

Amendment and Response to Non-Final Office Action, Submitted January 8, 2007

1. A gasket for a pre-filled syringe, the syringe comprising a barrel into which liquid is charged, wherein a peripheral side surface of the gasket that contacts an inner surface of the syringe barrel is provided with a restriction, wherein the restriction has a height at least one-third the length of the peripheral side surface, and wherein a periphery of a bottom surface of the gasket that is not for contact with the liquid is formed into a tapered slant, and wherein only the peripheral side surface that contacts the inner surface of the syringe barrel is laminated with polyethylene fluoride resin.

The Office Action states that it would have been obvious "to modify the Trull et al. gasket by using a gasket material of polyethylene, as taught by Sudo et al. ... to serve as a protective sealant coating for the gasket." However, as the Office Action concedes, Trull does not teach that a peripheral side surface of the gasket that contacts an inner surface of the syringe barrel is laminated with polyethylene fluoride resin. Trull does not teach or suggest gasket lamination at all.

Sudo teaches away from a laminated sliding stopper where the surface of sliding contact is not strictly 80-100% of the length of the peripheral side surface. The Sudo gasket is:

characterized in that the ratio of the length (Y) of the surface along which the outer circumferential part of the sliding stopper and the inner wall of the barrel are contacted to the length (L) of the sliding part of the sliding stopper, i.e. Y/L is in the range of 0.80 to 1.00 (col. 2, lines 16-21)

Sudo also states that:

In the present invention ... the length Y of the contact surface with the inner wall of a barrel is substantiall (sic) 80 to 100% of the length of the sliding surface. (col. 3, lines 29-34)

Application Serial No. 09/720,762

Attorney Docket No. 114474.00014

Amendment and Response to Non-Final Office Action, Submitted January 8, 2007

Indeed, Sudo describes only embodiments with a Y/L ratio in the range of 0.80 to 1.00. In addition, Sudo's Comparative Example 4 teaches that a laminated stopper with a Y/L ratio under 80% "meets with a problem in the physical tests" (col. 7, lines 37-40).

For at least the reasons discussed above, the references of record do not teach or suggest selectively laminating a gasket with an annular restriction as recited in amended claim 1.

## II. Independent Claims 9 and 23

As noted, independent claims 9 and 23 are also rejected under 35 U.S.C. § 103(a) as being unpatentable over the combination of Trull and Sudo.

Claims 9 is currently amended, and recites as follows:

9. A gasket for a pre-filled syringe, the syringe comprising a barrel into which liquid is charged, wherein a peripheral side surface of the gasket that contacts an inner surface of the syringe barrel is provided with a restriction, wherein the restriction has a height at least one-third the length of the peripheral side surface, and wherein the peripheral side surface that contacts the inner surface of the syringe barrel is laminated with polyethylene fluoride resin, and wherein a periphery of a bottom surface of the gasket that is not for contact with the liquid is formed into a first tapered slant, and a second tapered slant is formed between the peripheral side surface of the gasket that contacts the inner surface of the syringe barrel and the restriction.

Independent claim 23 is currently amended, and recites as follows:

23. A gasket for a pre-filled syringe, the syringe comprising a barrel into which liquid is charged, wherein a peripheral side surface of the gasket that

Application Serial No. 09/720,762

Attorney Docket No. 114474.00014

Amendment and Response to Non-Final Office Action, Submitted January 8, 2007

contacts an inner surface of the syringe barrel is provided with a restriction, wherein the restriction has a height at least one-third the length of the peripheral side surface, and wherein a periphery of a bottom surface of the gasket that is not for contact with the liquid is formed into a tapered slant, and wherein the peripheral side surface that contacts the inner surface of the syringe barrel is laminated with polyethylene fluoride resin.

For at the least reasons discussed in respect of independent claim 1, amended claims 9 and 23 are also patentable over the combination of Trull and Sudo.

### III. Independent Claim 33

Claims 33-37 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Trull et al. in view of Vacca (U.S. 5,531,255).

Independent claim 33 is currently amended, and recites as follows:

33. A gasket for a pre-filled syringe, the syringe comprising a barrel into which liquid is charged, wherein a peripheral side surface of the gasket that contacts an inner surface of the syringe barrel is provided with a restriction, wherein the restriction has a height at least one-third the length of the peripheral side surface, and wherein a periphery of a bottom surface of the gasket that is not for contact with the liquid is formed into a tapered slant, and wherein only the peripheral side surface that contacts the inner surface of the syringe barrel is laminated with silicon.

Independent claim 33, as amended, is patentable over the cited references. Trull does not teach gasket lubrication. Vacca does not teach or suggest selectively applying a

Application Serial No. 09/720,762  
Attorney Docket No. 114474.00014  
Amendment and Response to Non-Final Office Action, Submitted January 8, 2007

lubricant to a gasket surface. For at least the reasons discussed above, the references of record do not teach or suggest selectively applying silicon to a gasket with a restriction as recited in amended claim 33.

#### **IV. Dependent Claims**

Dependent claims 3, 6-8, 10-22, 24-32 and 34-40 are patentable with the independent claims set forth above. These dependent claims recite additional features that further distinguish the invention.

Application Serial No. 09/720,762  
Attorney Docket No. 114474.00014  
Amendment and Response to Non-Final Office Action, Submitted January 8, 2007

In view of the foregoing, Applicant respectfully submits that the claims are in condition for allowance and therefore requests reconsideration of the application. The Examiner may telephone Applicant's undersigned counsel at the number below concerning this application.

Also enclosed is a Petition for Extension of Time for three (3) months.

WILLKIE FARR & GALLAGHER, LLP

Dated: January 8, 2007

By: 

Leslie M. Spencer

Registration No. 47,105

WILLKIE FARR & GALLAGHER LLP

787 Seventh Ave.

New York, New York 10019

212-728-8782

212-728-9782 Fax